

## COLORADO DEPARTMENT OF HEALTH CARE POLICY & FINANCING

1570 Grant Street, Denver, CO 80203-1818 ◆ (303) 866-2993 ◆ (303) 866-4411 Fax John W. Hickenlooper, Governor ◆ Susan E. Birch MBA, BSN, RN, Executive Director

April 2, 2012

Barbara Edwards, Director
Disabled & Elderly Health Programs Group
Center for Medicaid and CHIP Services
Centers for Medicare & Medicaid Services
Department of Health and Human Services,
Attention: CMS-2345-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-2345-P Medicaid Program; Covered Outpatient Drugs

Dear Ms. Edwards:

I am writing to you on behalf of Colorado's single state Medicaid agency, the Department of Health Care Policy and Financing to provide comment related to CMS-2345 P *Medicaid Program; Covered Outpatient Drugs* proposed regulations to implement specific provisions of the Affordable Care Act.

Colorado recognizes the complexities of providing a regulatory framework for implementing changes to covered outpatient drugs in Medicaid and seeks clarification on the interpretation of 42 U.S.C. §1396r-8(b) with specific regard to active State supplemental drug rebate agreements. The plain language of the Affordable Care Act (ACA) provision suggests that the 100% federal portion of the revenue is intended to offset only the increase in revenue "attributable" to the increase in the federal minimum drug rebate level. Colorado, like many States, has active supplemental rebate agreements that result in rebate revenue in excess of the federal minimum rebate, half of which is retained by the State. In the case where a supplemental rebate exists, the increase in the federal minimum rebate reduces the size of the supplemental rebate, but does not result in an increase in revenue. Colorado strongly suggests that the proper interpretation of 42 U.S.C. §1396r-8(b) is that those existing State supplemental drug rebate agreement revenues are acknowledged and that the 100% federal portion is applied to drug rebate levels greater than those that would have been experienced by a State due to an active State supplemental agreement level, absent an increase to the federal minimum.

Additionally, based on Colorado's experience with calculation of Medicare Part D "clawback" amounts under the Medicare Modernization Act (MMA) of 2005, we strongly request that the calculated drug rebate offset amount attributed to increases in the federal minimums explicitly be subject to the provisions of 42 CFR §§ 430.45 and 430.42 for reconsideration of any reduction of federal Medicaid payments.

Colorado has specific comments on the proposed regulations as follows:

§447.509(c) Federal offset of rebates. Colorado is concerned that the calculation methodology for federal offset as expressed does not include a consideration of active State supplemental drug rebate agreements in effect in the quarter during which the drug was purchased by the State. Colorado strongly suggests that the calculation language be revised to acknowledge revenue attributable to existing State supplemental drug rebate agreements and to limit application of 100% federal portion to only revenue directly attributable to the increase in the federal rebate minimum.

§447.509(c)(5) Federal offset of rebates (proposed new). Please add a subparagraph (5) that clarifies the calculations resulting from the provisions of §447.509 (c)(1) through (4) are subject to the provisions of § 430.45. Colorado proposes the following language: Any reduction in supplemental drug rebate amounts to States that result from application of the 100% federal portion shall be considered a reduction of Federal Medicaid payments in accordance with §430.45 and shall be subject to §430.45 (b) *Right to reconsideration*.

Thank you for the opportunity to provide comment on concerns and suggested improvement to the proposed rules on covered outpatient drugs. Should you have any questions, I can be reached at Barbara.prehmus@state.co.us or via telephone at (303) 866-2991.

Sincerely,

Barbara B. Prehmus, M.P.H.

Federal Policy & Rules Officer

Cc: Ms. Susan E. Birch, MBA, BSN, RN, Executive Director

Ms. Lorez Meinhold, Deputy Policy Director, Governor's Office of Policy and Initiatives,

Colorado Governor John W. Hickenlooper

Ms. Cynthia Mann, Center for Medicaid and CHIP Services